

November 17, 2015

Outline of Purilum Comments to OIRA on Deeming Regulation

Economic Impact on Purilum and Similar ENDS Small Businesses

- 100% of Purilum customers would qualify as small tobacco product manufacturers under the Federal Food, Drug, and Cosmetic Act (i.e., fewer than 350 employees).
- All of Purilum's products were introduced into the domestic market after February 15, 2007, and it is unlikely that Purilum or its customers would have access to appropriate predicate products to cite in Substantial Equivalence (SE) reports for the products.
- This means that every individual product manufactured by Purilum (e.g., each flavor, nicotine level, packaging configuration, etc.)—and each future product developed by the company—will require individual approval via the Premarket Tobacco Application (PMTA) pathway.
- Even with clear guidance from FDA, the cost of preparing a PMTA could exceed a million dollars per product. Our trade coalition's initial PMTA cost estimate, based on an analysis by SciLucent, LLC, of the September 2011 draft PMTA guidance, ranges from \$1.3 million to \$3.5 million per new product.
- Purilum currently offers several thousand distinct products, meaning the costs could exceed \$3.5 billion dollars to develop the requisite PMTA applications for current offerings alone.
- The PMTA process would therefore eliminate our company and virtually all small manufacturers. FDA states as much in its RFA analysis for the proposed deeming regulation, acknowledging that it expects to receive only 25 PMTAs, which represents only 1.5% of the number of SKUs FDA underestimated were on the market in this category.
- Imposing the existing expensive and onerous PMTA regime on ENDS products, without the flexibility to account for the potential public health benefits such products could offer to smokers, could effectively hand the market to an oligopoly of larger manufacturers.
- The results of the 2014 proposal thus could include dramatic market consolidation, the loss of jobs for all 25 Purilum employees, the elimination of the Purilum business model, significant reductions in consumer choice and innovation, and a remigration of ENDS users back to combusted cigarettes.
- Extending the compliance deadline for small businesses like Purilum will not sufficiently reduce the burdens on us; it will merely delay our departure from the market.

Unintended Consequences of ENDS Regulation

- Small businesses like Purilum are often the types of entities that are at the forefront of product innovation, as FDA has seen repeatedly in the drug and device industry and is the case in the ENDS industry.
- If final regulations are not modified from the proposal, the marketplace may shift to the largest and most financially secure companies, although even they may not have the

resources or long-term scientific data to prepare successful PMTAs for their existing ENDS products.

- Removal of small businesses from the marketplace, thereby restricting the market for ENDS products, may have the unintended consequence of forcing millions of consumers back to smoking traditional cigarettes. Given the prevailing scientific opinion that non-combusted forms of nicotine are far safer than combusted cigarettes, FDA's proposal could prove devastating to the public health.
- The potential for tobacco harm reduction products, such as ENDS, to reduce the burden of smoking-related disease (i.e., reduced deaths, improved productivity, lower health care costs) may be very significant. FDA should not suppress this technology with overly burdensome regulation before its benefits have been fully realized.

Key Items for Final Deeming Regulation

1. Change Grandfather Date: FDA could use its enforcement discretion or rulemaking authority to move the February 15, 2007, date to the date of publication of the final deeming regulations, thus eliminating the most burdensome tasks of navigating the SE and PMTA processes for Purilum's currently marketed products. Using FDA's enforcement discretion in this manner does not undermine the Agency's stated mission of protection of public health, as these products would still be subject to many other regulatory requirements. This would also free up needed resources so that FDA can more quickly begin the process of developing product standards, testing standards, and GMPs. Finally, this would maintain competition in the marketplace as, without this change, only the large manufacturers would likely have a chance at survival.
2. Product Standards Rather than Premarket Approval for ENDS Products
 - Rather than applying the PMTA regime that Congress designed for traditional tobacco products to ENDS products, FDA should instead exercise its broad enforcement discretion to not require premarket submissions for ENDS products that meet product standards promulgated by FDA.
 - Based on the continuum of harm repeatedly acknowledged by FDA, and the growing body of evidence that ENDS products are a less harmful alternative to combustible products, FDA can conclude that permitting ENDS products that meet certain product standards to remain on the market would be "appropriate for the protection of public health."
 - Products that fail to meet the product standards would be subject to enforcement action for failure to comply with applicable standards and premarket review requirements. As an added measure, FDA could require the filing of a tobacco product standard compliance statement under penalty of perjury.
 - Timely implementation of basic product standards could benefit the public health faster and more effectively than a premarket approval system with a 24-month compliance period followed by a review period. For example, FDA could quickly halt the use of harmful ingredients such as diacetyl in e-liquids.

- Companies would need to file an abbreviated PMTA for ENDS products that deviate from the product standards.
- FDA should permit continued marketing of ENDS products until promulgation of final product standards with a compliance period allowing for product redesign or reformulation to meet such standards or submission of an abbreviated PMTA.
- Like the OTC Drug Review, this would enable the Agency to protect the public health in an efficient manner without requiring full PMTA submissions for each individual product, a process that could bring the Agency to a virtual standstill and decimate the marketplace for the smaller industry players like Purilum.
- Industry would assist FDA with convening expert panels to establish flavor standards for ENDS products.

3. Continue to Permit Flavored E-Liquids

- The majority of products offered by Purilum have flavors other than tobacco and menthol.
- Purilum understands that adult smokers permanently transitioning to ENDS products often prefer flavored products that do not taste like cigarettes and thus that flavored e-liquids can have a significant role to play in facilitating successful switches.
- Any restriction on flavored products included in the final deeming regulation would have significant economic consequences for Purilum and a potentially serious impact on the public health.
- From a legal perspective, in order to establish a tobacco product standard under section 907 of the Federal Food, Drug, and Cosmetic Act, FDA must find the standard in question “appropriate for the protection of the public health,” taking into account the impacts on both users and non-users.
- Purilum acknowledges the sensitivity of the issue and the concern that the marketing of certain flavored products could appeal to youth.
- However, on balance, due to the potential benefits of responsibly marketed flavored ENDS products, the scientific data would not support significant restrictions or an outright ban on flavored ENDS products.
- FDA also must not impose an effective flavor ban by setting an unreasonable standard for premarket approval of flavored products, thereby establishing a “backdoor” flavor ban.

4. Abbreviated PMTA Pathway: In addition or in the alternative to the standards approach, FDA could develop an abbreviated PMTA pathway for ENDS products. See attached Streamlined Pathways White Paper developed by our trade coalition, CITMA.

5. Develop Standard Reference Products for Use as “Predicates” in SE Process: As an alternative to changing the grandfather date, adoption of a standards-based approach, or creation of an abbreviated PMTA pathway, FDA (with input from industry) could establish standard reference ENDS products for companies to cite as “predicates” in SE reports. See attached Streamlined Pathways White Paper developed by our trade

coalition, CITMA.

6. Allow Minor Changes to Deemed Products: As in the medical device context, FDA could use its enforcement discretion to require new SE reports or PMTAs only for certain modifications rather than strictly enforcing the “new tobacco product” definition to include any and all changes, no matter how insignificant. A new SE order or PMTA should be required only where the modifications could significantly affect the risks presented by the product and FDA should provide specific guidance for manufacturers to conduct this analysis internally. See, e.g., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>. It is also essential that FDA permit package quantity changes without requiring SE/PMTA review or behavioral data to support such minor routine packaging changes.
7. Delayed Compliance Dates Tied to Publication of Final Guidance: If FDA provides for delayed compliance dates, the deadline for submissions such as PMTAs, SE reports, and HPHC testing reports should be set on the date that is 24 months from FDA’s publication of final guidance relating to the particular filing for the specific category of deemed products. Thus, for example, in order for a company to be covered by FDA’s compliance policy, a PMTA for an ENDS product would be due 24 months from the date of publication of a final guidance (after a comment period for the draft guidance) specifically relating to the content of PMTAs for ENDS products. If FDA follows this approach, submissions for ENDS products will be of higher quality, which will reduce the Agency’s workload and expedite the review process.